SEP 1 9 2000

K001768

2500 SANDERSVILLE ROAD
P.O. BOX 13550
LEXINGTON, KY 40511

US IOL INC.
We fit the world

PHONE (606) 259-4924 / 259-4925
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510(k) Summary

Device Trade or Proprietary Name: Occu-Flo™ Punctum Plugs

Device Common or Usual Name or Classification: Lacrimal Plug/Punctum Plug

Classification Name/Product Code(s): 86LZU, Punctum Plug

Predicate Devices: Surgidev Silicone Punctum Plug (Surgidev), Soft Plug (Oasis), Punctum Plug (FCI), Tapered-Shaft Punctum Plug (Eagle Vision & Ciba)

Device Description: A silicone ophthalmic device designed for insertion and retention in the punctum.

Device Use: Designed for enhancement of eye fluids by blocking the punctum. Useful for treatment of dry eye.

Classification: Class II, Ophthalmology

Comparison to Predicate Devices:

Device Name Features	U.S. IOL Occu-Flo™ Punctum Plugs	Surgidev Silicone Punctum Plug (Surgidev) 510(k) document control number K980844	Soft Plug (Oasis) 510(k) document control number K980437	Punctum Plug (FCI)	Tapered-Shaft Punctum Plug (Eagle Vision & Ciba)
Indications Claimed	Treatment of dry eye post op Enhance efficiency of medications Treatment of contact lens problems Adjunctive treatment aid	Treatment of dry eye after surgery Enhance efficiency of medications Treatment of contact lens problems Adjunctive treatment aid	Treatment of dry eye after surgery Enhance efficiency of medications Treatment of contact lens problems Adjunctive treatment air	Not Available	Treatment of dry eye
Function	Causes occlusion of punctum, resulting in greater tear retention	Causes occlusion of punctum, resulting in greater tear retention	Causes occlusion of punctum, resulting in greater tear retention	Causes occlusion of punctum, resulting in greater tear retention	
Design – Length Diameter (typical)		2.0mm 0.8mm	2.0mm 0.8mm	2.0mm 0.8mm	1.8mm 0.7mm
Material	Medical Grade Silicone	Medical Grade Silicone	Medical Grade Silicone	Medical Grade Silicone	Medical Grade Silicone

Clinical Tests: None
Adverse S & E Information: None

Teresa Burton

6/09/00

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2000

Ms. Teresa Burton
Manager
U.S. IOL, Inc.
2500 Sanderville Road
P.O. Box 13550
Lexington, KY 40511

Re: K001768
Trade Name: Occu-Flo™ Punctum Plugs
Regulatory Class: Unclassified
Product Code: 86 LZU
Dated: August 8, 2000
Received: August 9, 2000

Dear Ms. Burton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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510(k) Number: K001768

Device Name: **Silicone Punctum Plug**

Indications For Use:

The Occu-Flo™ Punctum Plug is intended for use in patients experiencing dry eye. The plug is designed to alleviate symptoms of dry eye by blocking the punctum.

The Occu-Flo™ Punctum Plug may be used in the treatment of various ocular diseases such as keratitis, red lid margins, recurrent corneal erosion, filamentary keratitis, corneal ulcers, blepharitis, conjunctivitis, and other external eye diseases.

The Occu-Flo™ Punctum Plug may be used postoperatively to enhance the retention of medications. The plug may also be used by contact lens wearers who are experiencing dryness.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Karen Warbington

Division Sign-Off
Division of Ophthalmic Devices
510(k) Number K001768